

Reflecting on the fifth anniversary of the first issue of *Bandolier*, and 60 issues, one of the big changes is how much easier it is now to answer interesting questions than it was five years ago. This month, for instance, we take a look at a range of questions readers asked of *Bandolier* in the last year.

Two, on acupuncture for back pain and the effect of aspirin prophylaxis on haemorrhagic stroke, were answered from published reviews. Two others, on the use of yoghurt for vaginal infections and *Helicobacter* eradication in dyspepsia, we were able to approach through a quick search of the literature. Two more, on folate (more properly multivitamin use) and colon cancer and the use of herbal remedies for irritable bowel syndrome, could be approached from a great prospective epidemiological study and a superb randomised trial.

Five years has seen a revolution in the quick availability of information and knowledge. The Cochrane Library leads this, because we can have access to 250,000 controlled trials on our desk-top computers. If we have Internet access, PubMed gives easy access to up-to-date searching for most top journals we care to examine. And thousands of researchers put in huge numbers of hours into doing systematic reviews and meta-analyses or exquisite randomised trials to answer questions for us.

"No one means all he says, and yet very few say all they mean, for words are slippery and thought is viscous". We may be better at producing knowledge, and better quality knowledge, but there is still the problem for the ordinary doctor, or nurse, or biochemist, or whatever, in knowing that even some of the many things they do every day is of the best. The chasm between best knowledge and best implementation remains, and will take some closing.

*Bandolier*, and others, are looking at better ways of making the knowledge more readily available to make closing the gap easier. More in coming months, but check on Stop Press on page 8 for a glimpse of what the future might hold.

## ACUPUNCTURE FOR BACK PAIN?

*Bandolier* well remembers a television programme in which an acupuncturist blithely claimed that acupuncture could "cure" 60% of all chronic back pains. A bit over-the-top, we thought at the time, but we all know someone who claims to have been "cured" by acupuncture, or by medical interventions of which we are sceptical. A systematic review of acupuncture in back pain [1] is therefore a welcome relief from ignorance when it helps make sense of a difficult subject.

### Searching

Very considerable efforts went into trying to find all the trials. These included MEDLINE, Cochrane Library, and a database specialising in complementary medicine. Authors publishing within the last five years or so were also contacted.

### Included studies

Studies were selected on the basis that they were randomised, that dry needles were inserted into the skin, and which was described by the authors as acupuncture. Studies were assessed methodologically both in terms of methodological quality (randomisation, blinding, withdrawals) and on the quality of the acupuncture as judged independently (and blind) by six experienced medical acupuncturists.

Most of the included studies used sham acupuncture as control, though waiting list controls and lidocaine injections were also used. The outcomes were almost always short-term pain relief, as judged by the patient in some instances, and by the practitioner in others. There were few long-term outcomes.

### Results

Of the twelve included studies, only four were blinded. Adequacy of acupuncture was judged (on a 0-2 scale, where 2 is best) as 2 in one, 1 in eight and 0 in three. Not all these studies had extractable outcome data.

Four blinded studies showed no difference from control (Figure, Table). Fifty-seven percent of patients improved with acupuncture and 50% with control, a relative benefit of 1.2 (95% confidence interval 0.9 to 1.5). The number needed to treat with acupuncture for one patient with back pain to achieve a short-term improvement was 13 (95% confidence interval 5 to no benefit).

Five non-blinded studies did show a difference from control, with 67% improved with acupuncture and 38% with control. Here the relative benefit was significant at 1.8 (1.3 to 2.4) and the NNT was 3.5 (2.4 to 6.5).

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*The views expressed in Bandolier are those of the authors, and are not necessarily those of the NHSE*

## Effects of acupuncture on short-term outcomes in back pain

Type of study	Number of trials	Improved with acupuncture (%)	Improved with control (%)	Relative benefit (95% CI)	NNT (95%CI)
Blind	4	73/127 (57)	61/123 (50)	1.2 (0.9 to 1.5)	13 (5 to no benefit)
Non-blind	5	78/117 (67)	33/87 (38)	1.8 (1.3 to 2.4)	3.5 (2.4 to 6.5)

### Comment

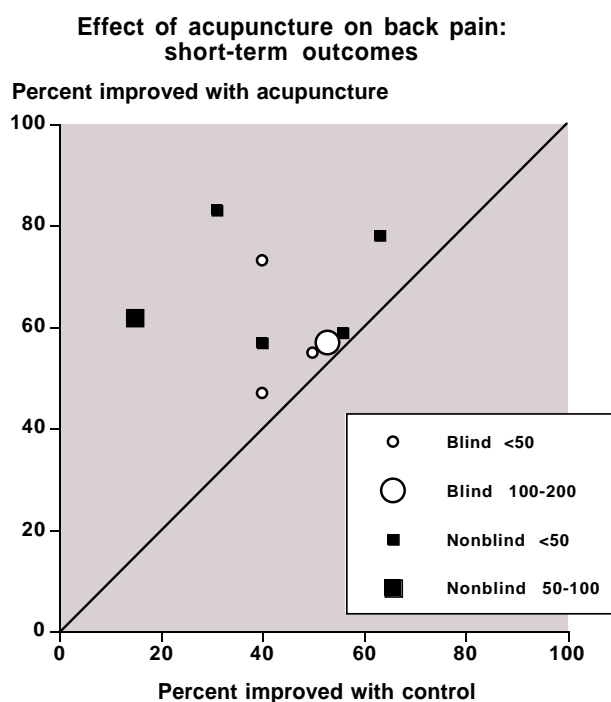
Acupuncture trials are often difficult to assess. There are issues of whether the acupuncture has been done correctly, about the appropriateness of control interventions, whether trials can be truly blinded, and about the relevance of outcomes. Ernst & White have examined these in their review, and make thoughtful comments on all of them.

Perhaps the biggest problem is that these trials, as a group, have avoided the hard question of longer-term outcomes. Even if acupuncture provides short-term relief, its place in management of back pain remains unknown.

The question is whether this review provides evidence of lack of effect, or lack of evidence of effect. The inability of the four highest quality blinded trials to show a statistically significant short-term improvement must be worrying for those providing acupuncture services, and for the health services or individual who purchase acupuncture. A sceptical view seems to be most appropriate until trials of high quality prove that to be wrong.

Reference:

- 1 E Ernst, AR White. Acupuncture for back pain: A meta-analysis of randomised controlled trials. Archives of Internal Medicine 1998 158: 2235-2241.



## YOGHURT AND VAGINAL INFECTIONS

*Bandolier* is frequently asked the questions "What is the evidence for X"? A frequently asked question concerns the use of yoghurt for vaginal infections. Where's the evidence? How good is it? We know it works, so why don't you write about it? The answer is usually that there are no systematic reviews (that we can find) and few large, randomised trials. That's about where we are with yoghurt and vaginal infections.

We need to ask three questions:

1. What is the problem for which we seek an answer?
2. What is the intervention that might solve the problem?
3. How do we know when the problem has been solved?

### Defining vaginal infection

Bacterial vaginosis is the most common type of vaginal disorder. It is found in about 10% of women and in as many as 30% in selected clinical populations. Perhaps half the women with the disorder have no or mild symptoms. The chief complaints are increased vaginal discharge, especially after coitus or

menstruation. This is sometimes accompanied by a fishy odour caused by bacterial breakdown of amino acids. There may be vulvar irritation also.

### Treating vaginal infection

A particular feature of bacterial vaginosis is the reduction or absence of lactobacilli in the vaginal flora. Yoghurt (or "live" yoghurt, anyway) is full of lactobacilli, hence the logic in its use. Other sources of lactobacilli are freeze-dried capsules. The principal is that this restores vaginal lactobacillus and hence pH levels, thus making it difficult for the unwanted organisms and symptoms to persist. Antibiotics are a more conventional way of treating vaginal infection.

### Defining a cure

There are a number of standard ways of generating a clinical diagnosis of vaginal infection. They include:

1. Presence of a whitish discharge.
2. Vaginal pH above 4.5.
3. Presence of clue cells on a smear.
4. Positive test for amines.

## Summary of studies of Lactobacillus on treatment of vaginal infection

Reference	Clinical Indications and patient characteristics	Trial design	Intervention	Definition of cure	Time of measurement	Result
<b>Treating active disease</b>						
Fredricsson et al, 1989	84 women with at least 3 of 4 criteria positive	Randomised four active treatments	5 mL fermented milk product 5 mL acetic acid jelly 5 mL oestrogen cream 500 mg metronidazole vaginal tablets Two daily doses for 7 days	≤1 criterion	4 weeks	1/13 fermented milk 3/15 acetic acid jelly 1/16 oestrogen cream 13/15 metronidazole
Hallén et al 1992	60 women attending STD clinic with 3 of 4 criteria positive	Randomised, double-blind, placebo-controlled	Freeze-dried lactobacillus acidophilus capsules versus starch placebo, twice daily for six days	≤1 criterion	End of treatment	10/13 Lactobacillus 3/12 placebo
Neri et al, 1993	84 women in 1st trimester, with 3 of 4 criteria positive	Randomised comparison with acetic acid tampons	10-15 mL Lactobacillus acidophilus yoghurt two doses for seven days, and repeated one week later Vaginal tampon soaked in 5% acetic acid	≤1 criterion	4 weeks	28/32 yoghurt 12/32 acetic acid
Parent et al, 1996	32 non-menopausal women, 8 of whom were pregnant, with at least 2 of 4 criteria positive	Randomised, placebo-controlled	Freeze-dried Lactobacillus acidophilus capsules with 30 µg oestradiol versus starch placebo, one to two daily for six days	≤1 criterion	Day 15 after start of therapy	16/28 Lactobacillus 0/29 placebo
<b>Preventing disease recurrence</b>				Definition of disease		
Reid et al, 1992	41 women with acute lower urinary tract infection	Randomised, blinded study	Antibiotics followed by freeze dried Lactobacillus Antibiotics followed by sterilized skim milk Twice weekly suppositories for two weeks and then once a month for two months	Recurrence of UTI by urine culture	Over 6 months	3/14 Lactobacillus 8/17 skim milk
Baerheim et al, 1994	47 women reporting 3 or more episodes of lower urinary tract infection over previous 12 months	Randomised, double-blind, placebo-controlled	Suppositories of Lactobacillus casei v. rhamnosus or placebo twice weekly for 26 weeks	Recurrence of UTI by urine culture and symptoms	Over 6 months	No difference in infection rates between the two groups.

If three or more are positive, then vaginosis is present. If there is one or none, then that constitutes a cure.

## Searching for evidence

*Bandolier* did a quick search on the Cochrane Library looking for treatments with yoghurt or lactobacillus-containing products compared with placebo. We found six randomised controlled trials looking at treatment of bacterial infections, and none on yeast infections.

## Treating active infection

Four trials looked at intravaginal treatment of a current episode of bacterial vaginosis (Table). Unless otherwise stated, successful treatment was a reduction from three or more bacterial vaginosis clinical criteria reduced to one or none.

The results are shown in detail in the Table. Fredricsson and colleagues [1] used a fermented milk product twice daily for seven days in comparison with other treatments, including metronidazole. At 4 weeks, only 1/13 patients had been successfully treated with fermented milk, which compared unfavourably with the antimicrobial metronidazole (13/15 patients successfully treated).

Hallén [2] used lyophilised Lactobacillus acidophilus twice daily for six days. They reported a success rate of 10/13 immediately after treatment compared with 3/12 with placebo. This benefit was almost entirely lost after the next menstrual bleed.

Yoghurt was actually only used in one study [3]. During the first trimester of pregnancy, a regimen of intravaginal yoghurt twice daily for 7 days, with the regimen repeated a week later

produced impressive results. On the second day of treatment all 32 yoghurt patients reported subjective feelings of improvement. Using the absence of clinical criteria at one month, 28/32 of the yoghurt group remaining free of bacterial vaginitis, compared with 12/32 treated with acetic acid group.

An open randomised controlled trial [4] of 32 pregnant and non-pregnant women looked at 50-100 mg of a lyophilisate of one selected strain of hydrogen peroxide-producing Lactobacillus acidophilus plus 0.03 mg of oestriol daily. Entry criteria were less strict, with a minimum of two of four clinical criteria present instead of the usual three. At two weeks lactobacillus was significantly more effective than placebo with 16/28 cured with lactobacillus compared with 0/29 with placebo.

## Preventing reinfection

Two trials looked at whether lactobacillus is useful in preventing recurrence of infection, though the concentration was on urinary tract infection, rather than just vaginal infection.

One trial [5] looked at lactobacillus treatment to prevent recurrence of urinary tract infection (UTI) after antimicrobial treatment of UTI with an antibiotic. Women were randomised to use lactobacillus suppositories or a sterilised skimmed milk placebo twice weekly for two weeks, then once monthly for two months. Recurrence rates were collected over 6 months. With lactobacillus 21% (3/14) had a recurrence compared with 47% (8/17) with placebo.

Another trial [6] followed women who suffered frequent UTIs over a 6-month period. During this time women had twice weekly doses of Lactobacilli casei v. rhamnosus or placebo. There was no statistically significant difference in

monthly infection rates, which were 0.21 (95% CI 0.15 to 0.28) for lactobacillus and 0.15 (0.09 to 0.21) for placebo.

## Adverse effects

Two trials reported on adverse effects with lactobacilli suppositories. In both cases there were no serious side effects. One trial [4] reported one case of disagreeable and burning sensations with active treatment. The second trial [6] reported messy discharge in four actives and one control.

## The bottom line

The bottom line is that these trials do not constitute enough evidence to recommend using yoghurt or Lactobacillus to cure vaginal infections. At best they may have some effect in ameliorating symptoms of bacterial vaginosis. The negative trial [1] looked at the outcome three weeks after the end of treatment. Other studies used endpoints much closer to the end of treatment, and were positive.

For suppressing urinary tract infections, there is no evidence of any effect.

## References:

- 1 B Fredricsson, K Englund, L Weintraub, A Olund, C Nord. Bacterial vaginosis is not a simple ecological disorder. *Gynecol Obstet Invest.* 1989 28: 156-60.
- 2 A Hallén, C Jarstrand, C Pahlson. Treatment of bacterial vaginosis with lactobacilli. *Sex Transm Dis.* 1992 19: 146-8.
- 3 A Neri, G Sabah, Z Samra. Bacterial vaginosis in pregnancy treated with yoghurt. *Acta Obstet Gynecol Scand.* 1993 72: 17-9.
- 4 D Parent et al. Therapy of bacterial vaginosis using exogenously-applied Lactobacilli acidophili and a low dose of estriol: a placebo-controlled multicentric clinical trial. *Arzneimittelforschung.* 1996 46: 68-73.
- 5 G Reid, A Bruce, M Taylor. Influence of three-day antimicrobial therapy and lactobacillus vaginal suppositories on recurrence of urinary tract infections. *Clin Ther.* 1992 14: 11-6.
- 6 A Baerheim, E Larsen, A Digranes. Vaginal application of lactobacilli in the prophylaxis of recurrent lower urinary tract infection in women. *Scand J Prim Health Care.* 1994 12: 239-43.

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## H PYLORI ERADICATION FOR DYSPEPSIA

While eradication of *Helicobacter pylori* now has an established place in treatment of peptic ulcer, whether it makes any difference in nonulcer dyspepsia remains in question. A review, which looked at a number of early studies, concluded that the evidence was thin [1], though the studies included at that time were rather poor in eradicating *Helicobacter*.

We now have several randomised trials of *Helicobacter pylori* eradication in non-ulcer dyspepsia. If you read the titles and abstracts, it seems that some of them say it works, while others say it doesn't. As usual, it's a bit more complicated than that. Though it may be early days, with three solid trials published, it may be time to visit them and see what sort of evidence is emerging.

## Trials

Three randomised trials have been published in recent months [2-4]. The main details of the trials are shown in the Table, all of which randomised patients between treatments that had an active eradication and placebo arm. They all used roughly the same types of patients, with roughly the same severity of disease, used roughly the same intervention and examined roughly the same type of outcome 12 months afterwards.

Two of the studies [3,4] reported as a primary outcome the number of patients who had complete resolution of symptoms one year after treatment, which is a high hurdle of effectiveness.

## Results

### McColl et al, 1998 [2]

This study concluded that treatment was effective. One year after treatment 33/154 patients (21%) with eradication therapy were symptom free, compared with 11/154 patients (7%) with placebo antibiotics. This was statistically significant – relative benefit 3.0 (1.6 to 5.7), and NNT of 7 (4.6 to 15).

The paper reported a change in symptom scores from a mean of about 11.5 out of a maximum of 20 at baseline to a mean of 5.4 with omeprazole and antibiotics and 6.2 with omeprazole and placebo. There was a corresponding reduction in antiulcer drug prescribing, from 84% to 43 % of patients in the omeprazole and antibiotic group, and from 80% to 53% of patients in the omeprazole and placebo group.

### Blum et al, 1998 [3]

This study concluded that treatment was ineffective. One year after treatment 45/164 patients (27%) with eradication therapy were symptom free, compared with 34/164 patients (21%) with placebo antibiotics. The relative benefit was 1.3 (0.9 to 2.0) and the NNT point estimate 15 (6.3 to no benefit).

The mean symptom score fell from a mean of about 3.3 out of 7 to about 1.7 in both groups. Endoscopically judged healing of gastritis was much better with omeprazole and antibiotics than with omeprazole and placebo. Of antibiotic treated patients, 123/164 (75%) were healed at one year compared with 5/164 (3%). The NNT for one year gastritis healing was 1.4 (1.3 to 1.5).

## Randomised trials of H pylori eradication for dyspepsia

	McColl et al, 1998	Blum et al, 1998	Gilvarry et al, 1997
Included patients	Referred to dyspepsia clinic by GP. H pylori positive with clinical symptoms of dyspepsia	Patients seeking medical care for persistent dyspepsia present for at least 6 months and no history of peptic ulcer disease	Patients attending a dyspepsia clinic who were H pylori positive and had symptoms for at least 3 months
Exclusions	Previous peptic ulcer disease, endoscopic oesophagitis, NSAIDs, gastric surgery	No ulcers, oesophageal or duodenal erosions, or Barret's oesophagus	Documented peptic ulcer, NSAIDs, previous upper GI surgery
Age (years)	17 - 70, mean 42	18 - 79, mean 47	18 - 72, mean 39
Sex distribution	about 50:50	41% male	28% male
Number of patients	318	328	100
Duration of dyspepsia	61% > 2 years	81% >1 year	at least 3 months
Severity of symptoms	11.5 on scale of 0 - 20	3.3 on scale of 0 - 7	14 on a scale of 0 -20
Main outcome	Resolution of symptoms (0 or 1 on range of 0 to 20)	Resolution of symptoms (score of 0 or 1 on range 0 - 20 in preceeding week)	Symptom score (means, no individual patient data)
Treatment	Omeprazole plus antibiotics versus omeprazole plus placebo	Omeprazole plus antibiotics versus omeprazole plus placebo	Bismuth plus antibiotics versus bismuth plus placebo
Time of outcome	12 months	12 months	12 months

### Gilvarry et al, 1997 [4]

No NNTs from this report, as only mean data were reported. In patients in whom *Helicobacter* was eradicated, mean symptom scores fell from 14.2 to 9.2. This was a significant change, but with placebo there was no significant improvement in symptoms, which were 12.6 at baseline and 10.0 at one year.

### What are we to make of this?

Firstly, patients benefited. In the first two trials about a quarter of patients treated with omeprazole and antibiotics were symptom free one year after treatment, compared with 14% with omeprazole alone. In all the trials the mean symptom score fell, whether treated with eradication therapy or no.

There were other benefits as well, though not quantified. Peptic ulcers occurred in four patients in the placebo group and none in the eradication group in one trial [2], six in the placebo group and one in the eradication group in a second [3], and in seven patients who were noted as eradication failures in the third [4]. This is not conclusive, but has biological plausibility when we know that endoscopic gastritis was so effectively treated by the eradication regimen [3].

Finally there is a cost argument. What scanty evidence we have from one study [2] is that consumption of acid suppressing medicine falls. This can be an expensive business, and an economic analysis might show that treatment benefits patients and saves money too.

### Comment

Does this add up to a sufficient weight of evidence, or should we be concerned about a negative trial, albeit with some positive aspects. Difficult, isn't it? The combined NNT of 9 (6 to 23) for H pylori eradication in nonulcer dyspepsia for complete symptom relief at one year is on the cusp of action.

We probably have enough information to be sure that *Helicobacter* eradication is effective (statistically). We need more information to be sure how well it works. There are issues here about testing, endoscopy, and patient age. This is something on which we need some sensible guidelines soon.

### References:

- 1 SJO Veldhuyzen van Zanten, PM Sherman. Indications for treatment of *Helicobacter pylori* infection: a systematic overview. Canadian Medical Association Journal 1994;150: 189-98.
- 2 K McColl et al. Symptomatic benefit from eradicating *Helicobacter pylori* infection in patients with nonulcer dyspepsia. New England Journal of Medicine 1998 339: 1869-1874.
- 3 AL Blum et al. Lack of effect of treating *Helicobacter pylori* infection in patients with nonulcer dyspepsia. New England Journal of Medicine 1998 339: 1875-1881.
- 4 J Gilvarry et al. Eradication of *Helicobacter pylori* affects symptoms in no-ulcer dyspepsia. Scand J Gastroenterol 1997 32: 535-540.

## OXFORD MASTERS PROGRAMME IN EBHC

The University of Oxford Centre for Continuing Professional Development's integrated postgraduate programme on evidence-based health care for professionals in the NHS has intakes several times a year. The programme integrates core elements of evidence-based health care into a coherent basis of expertise and competence in using and establishing evidence of health care effectiveness and efficiency.

The Masters Programme has a layered approach with three related courses - Certificate, Diploma, and MSc. Certificates lead to Diploma which lead to a Master of Science degree from the University of Oxford.

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# ASPIRIN AND STROKE

Because of its antiplatelet actions, aspirin is now well established in preventing subsequent myocardial infarction and ischaemic stroke in patients with a range of cardiovascular conditions. Some studies have suggested that it may increase the risk of haemorrhagic stroke, and so a meta-analysis of studies has been done [1] to try and measure this risk.

## Search

The authors performed extensive searching for randomised studies of aspirin versus control and which had stroke as an outcome. To be included studies had to have:

- ◆ Random allocation to aspirin or control.
- ◆ No intervention difference other than use of aspirin.
- ◆ Duration of at least 1 month.
- ◆ Information on stroke subtypes.

## Results

They found 16 trials with over 55,000 subjects. The mean aspirin dose was 273 mg/day (range 75 - 1500 mg/day) and the mean duration of treatment was 37 months (1 to 72 months). The study was predominantly in white men (88% men, 99% white) with a mean age of 59 years.

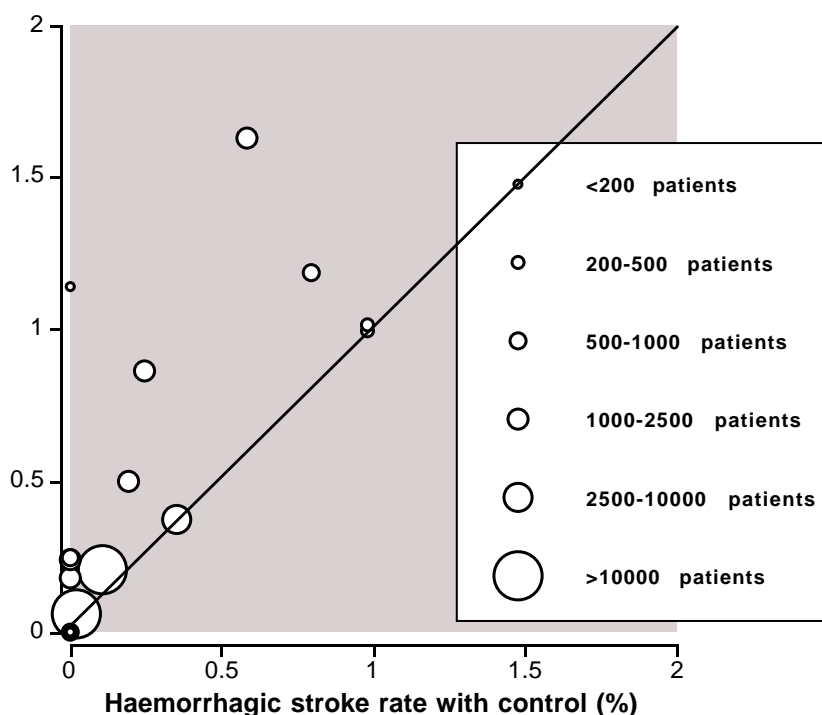
The 16 studies differed in size and the rate at which haemorrhagic stroke was found (Figure). Overall the rate was 0.26% with aspirin and 0.12% with control. This translates into a number needed to harm with aspirin to cause a haemorrhagic stroke of 715 (95% CI 471 to 1483).

But the rate of ischaemic stroke was lower (1.68%) with aspirin than with control (2.14%). The number needed to treat with aspirin to prevent an ischaemic stroke was 217 (145 to 428).

For all strokes, including some that were unclassified, the

## Aspirin and haemorrhagic stroke

Haemorrhagic stroke rate with aspirin (%)



balance was favourable. With aspirin 2.46% of patients had a stroke, compared with 2.76% with control. This is a number needed to treat to prevent any type of stroke of 335 (177 to 3043).

## Comment

Even in this large analysis of 55,000 people, there were only 108 cases of haemorrhagic stroke. It seems reasonable to conclude that although there is a slight increase in the rate of haemorrhagic stroke in patients treated with aspirin, this is outweighed by the benefit conferred by the reduction in ischaemic strokes, which were far more numerous.

Reference:

- 1 J He, PK Whelton, B Vu, MJ Klag. Aspirin and risk of hemorrhagic stroke. A meta-analysis of randomized controlled trials. JAMA 1998 280: 1930-1935.

## Effect of aspirin on haemorrhagic, ischaemic and total stroke

Stroke subtypes	Stroke with aspirin (%)	Stroke with control (%)	Absolute risk/benefit per 10,000 (95%CI)	Number needed to harm or treat (95%CI)
Haemorrhagic	75/28570 (0.26)	33/26892 (0.12)	12 (5 to 20)	715 (471 to 1488)
Ischaemic	480/28570 (1.68)	576/26892 (2.14)	-39 (-17 to -61)	217 (145 to 428)
Total stroke	703/28570 (2.46)	742/26892 (2.76)	-31 (-5 to -51)	335 (177 to 3043)

# FOLATE AND COLON CANCER

*Bandolier* 57 highlighted the importance of homocysteine for heart disease, and the role of dietary folate in reducing both homocysteine levels and heart disease. Folate, especially from multivitamin use, is also implicated as a factor in reducing risks of colon cancer [1].

## Study

In 1980, 88,756 women gave detailed information on their dietary habits, including their use of multivitamins, with regular updates over subsequent years. There was also information available on demographics, and smoking, physical activity, aspirin use, colonoscopy and parental history of colorectal cancer.

Up to 1994 there were 655 new cases of colorectal cancer, 442 in the colon, 143 in the rectum and 70 at undetermined sites. The way in which these cases were distributed according to folate intake was subjected to detailed scrutiny.

## Results

High total intake of folate in 1980 was inversely related to the risk of colon cancer (Figure 1), even after making adjustments for almost 20 possible confounding factors. This was also the case after allowing for possible confounding factors from other nutrients that were included in multivitamins.

When the risk was examined for multivitamin use, it became clear that the benefits of folate supplementation only became significantly apparent for 15 years of use, though there was a distinct trend after five years (Figure 2).

## Comment

This paper has examined the association between folate intake and colon cancer in this large cohort of women from many different angles. It may just be wrong, but that is unlikely. There is supporting evidence showing that high folate intake is associated with reduced colon cancer risk from other studies.

The bottom line with homocysteine and heart disease was eat well and take a multivitamin a day. With the potentially very large reductions in colon cancer also on offer, although perhaps after some time, this makes even more sense as part, with exercise, of a healthy living programme.

A particular feature of the paper is that it seeks and discusses some basic features of carcinogenesis and how folate intake may affect this. This puts a biological plausibility on the tale, which, with its cautious exploration of potential limitations, makes for a gripping read uncommon in scientific papers.

Reference:

- 1 E Giovannucci et al. Multivitamin use, folate, and colon cancer in women in the nurses' health study. *Annals of Internal Medicine* 1998 129: 517-524.

Figure 1: Effect of folate intake in 1980 on risk of developing colon cancer

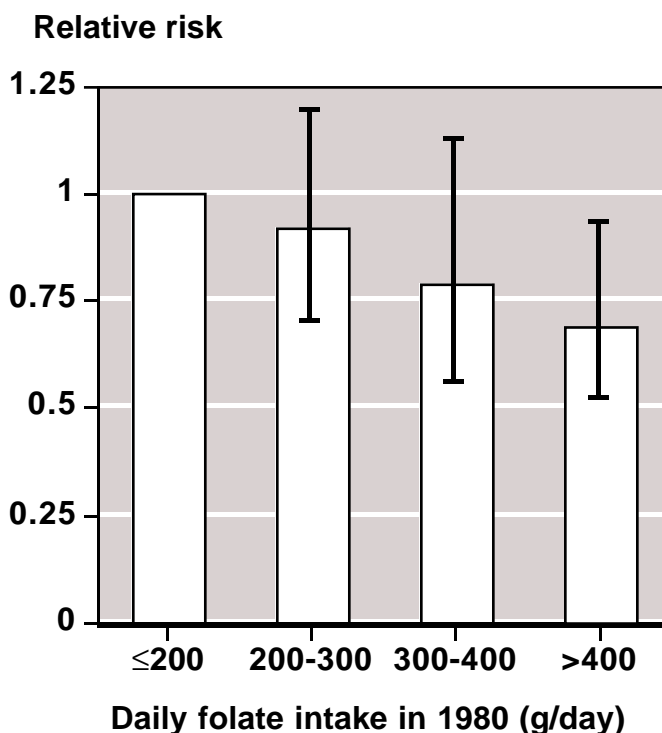
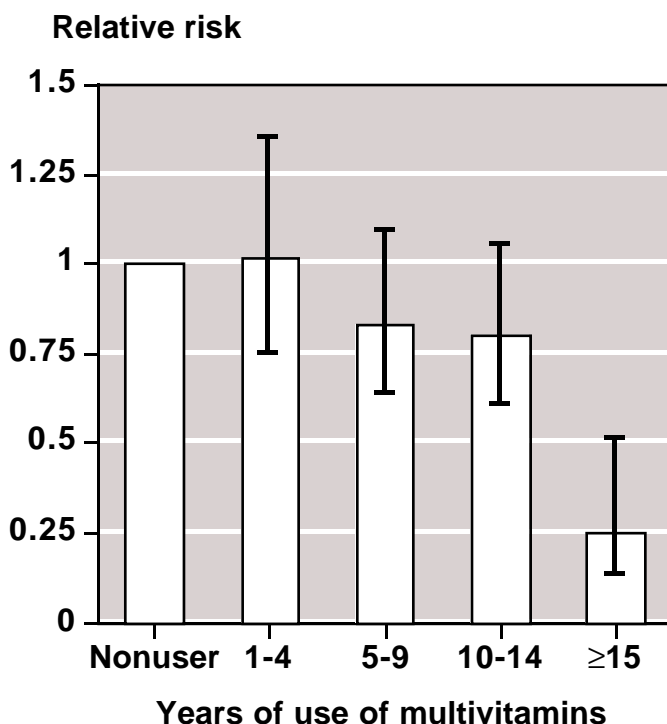


Figure 2: Effect of duration of multivitamin use on risk of developing colon cancer



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ISSN 1353-9906

# HERBAL MEDICINE FOR IBS

As many as 20% of the population may suffer from irritable bowel syndrome (IBS) at some time or another. It is characterised by recurrent or chronic abdominal pain, with distension and disturbed defecation. Many people just live with it, but for some it has a large impact on their lives.

It is a condition for which many people seek alternative therapy, often without any clear evidence. For the use of Chinese herbal medicine, a new, high-quality randomised trial [1] provides good evidence for effectiveness.

## Design

This trial randomised people with IBS to receive a placebo, or standard or individualised Chinese herbal medicine. The trialists went to a great deal of trouble to ensure the high standard of the study:

- ◆ They ensured that the herbal medicines used both for standard treatment and for individualised treatment came from a common Chinese herbal pharmacopoeia.
- ◆ They ensured that placebo was similar in taste and appearance to the Chinese medicine.
- ◆ They made the waiting time for medicines standard.
- ◆ They used a standard diagnosis for IBS
- ◆ They used standard scales for IBS symptoms and severity.
- ◆ They used patient and gastroenterologist scoring independently.
- ◆ They used blinded evaluators.

After two weeks run in, patients were randomised, and then saw their herbal practitioner at two-week intervals for two occasions, and then monthly for a further two occasions, with continuous treatment for 16 weeks in all. At the end of 16 weeks there was a rating of success (improved, same, worse) by patient and gastroenterologist.

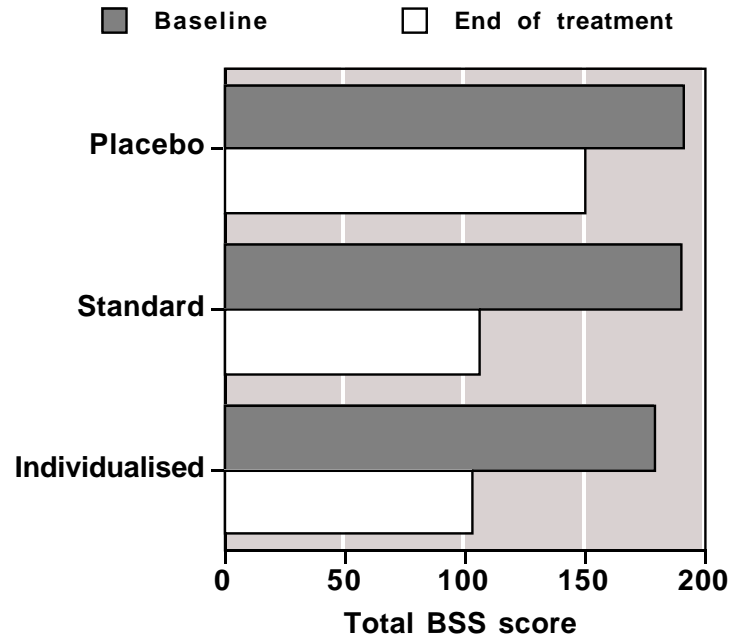
## Results

A bowel symptom scale (BSS) was used to assess change in IBS symptoms. It consisted of 100 mm visual analogue scales measuring pain/discomfort, bloating, constipation and diarrhoea. Over 16 weeks there was a significant reduction in BSS as judged by patients for standard and individualised Chinese herbal medicine treatments, but not for placebo (Figure).

At the end of 16 weeks 29/38 patients judged their IBS to have improved on standard treatment, 18/28 on individualised treatment, and 11/33 on placebo. This gives NNTs for IBS improvement after 16 weeks of treatment of 2.3 (95%CI 1.6 to 4.6) for standard treatment and 3.2 (1.8 to 14) for individualised treatment.

Adverse effects were minor, with two patients withdrawing from the treatment because of discomfort with the Chinese herbal treatments.

## Effect of Chinese herbal medicine on bowel symptom scale



## Comment

This was probably the first study of Chinese herbal medicine that both adhered to the principles of Chinese herbal medicine and to accepted principles of methodological rigour. The result was positive - not just positive, but with high levels of statistical significance.

Don't ask *Bandolier* what was in the Chinese herbal medicine, but if you want to know, a list of the 20 components of the standard treatment is to be found in the paper. We do not know whether such a medicine can be obtained commercially, but the lesson is that for some people with irritable bowel syndrome, Chinese herbal remedy may offer a welcome amelioration of symptoms.

### Reference:

- 1 A Bensoussan, NJ Talley, M Hing et al. Treatment of irritable bowel syndrome with Chinese herbal medicine. A randomized controlled study. JAMA 1998 280: 1585-1589.

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### *Bandolier* volume 1-20: PDF available

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